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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,379	10/06/2003	Donald R. VanDeripe		3529

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EXAMINER	
LOPEZ, AMADEUS SEBASTIAN	
ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/678,379	VANDERIPE, DONALD R.	
	Examiner	Art Unit	
	Amadeus S. Lopez	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 11/03/2005 have been fully considered but they are not persuasive. Although Garret includes carbon dioxide as an obligate component in each of his claimed gas mixtures, In column 1, line 65 to column 2 line 7, Garret discloses that it is well known in the art that "a helium:oxygen mixture of 80:20 volume has been shown to reduce pulses paradoxus and increase peak expiratory flow in patients with acute asthma... An additional benefit of a helium oxygen mixture is that when administered to patients with an acute myocardial infarction (disclosed by applicant to be a heart attack on page 4, line 6), the myocardium appears to be stabilized reducing the risk of ventricular arrhythmias." Therefore Garret already teaches a helium-oxygen mixture to treat patients that have suffered from a myocardial infarction. With regards to the argument made by the applicant on page 2 that Garret does not indicate anywhere in his specification that exhaled gases need to be shunted to ambient atmosphere, this is not necessary for him to do so because it is inherent that when a patient or animal exhales, expired gas is shunted or released into the ambient atmosphere. With regards to the argument made by the applicant that Garret does not specify the need to use a one way flutter valve to achieve nitrogen exhalation and washout, this is also unnecessary for him to disclose that since at no point in claim 1 or 2, does the applicant claim the use of a one way flutter valve within the claimed method. With regards to the arguments made on page 3, although the word tabulations

supposedly indicate that Garret was primarily directed at administration of gas mixtures containing carbon dioxide for use in treating asthma and for MRI imaging and that the statement made by Garrett stating that helium-oxygen mixtures are used to treat patients that have suffered from a myocardial infarction is of little relevance, as stated above in column 1, line 65 to column 2 line 7, Garret discloses that the delivery of a helium-oxygen mixture which is the basis for this invention, is well known in the art to treat patients that have suffered from a myocardial infarction and therefore it would be remain obvious to one of ordinary skill in the art to use such a gas mixture to treat patients that have suffered from a stroke or heart attack.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. The disclosure is objected to because of the following informalities:

On page 1, in line 4 of the background of the invention “it’s” should be deleted and replaced with -- its --.

On page 7, in line 2 the word "breath" should be deleted and replaced with --breathe--.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6001332 to Garret in view of Textbook of Medical Physiology, 1981 to Guyton in further view of US Patent No. 6899103 to Hood et al.

5. **With regards to claims 1 and 2,** what is taught by Garret is a method of inhalation of specific gas mixtures in a human patient with exhaled gases being shunted into the ambient atmosphere (inherent that exhaled gases from a patient are shunted into the ambient atmosphere), wherein the specific gas mixtures consist only as

complimentary concentrations of 20-100% oxygen and 0-80% helium and are devoid of nitrogen (Col. 1, line 65 to column 2 line 7; where it is stated by Garret it is well known in the art that when a helium:oxygen mixture of 80:20 volume percent is administered to patients with an acute myocardial infarction (heart attack; claim 2 of instant application), the myocardium appears to be stabilized reducing the risk of ventricular arrhythmias). What is not disclosed by Garret is delivering the helium:oxygen gas mixture to effect a 50-90% or more washout of nitrogen gas from the body, body water, ischemic tissues, and mitochondria in order to allow the reuptake of oxygen into hypoxic mitochondria and restore oxidative metabolism to affected tissues following a reversible vascular occlusions in a cerebrovascular accident, the administration of said gas mixture being from a suitable supply source and being implemented during patient transport or upon admission to the hospital as quickly as possible following the vascular event and continued for a minimum of 20 minutes up to 72 hours to assure optimum therapy and minimize cell death. What is taught by Guyton is the use of a decompression chamber, or hyperbaric chamber, to treat a diver who has been beneath the sea long enough so that large amounts of nitrogen have dissolved in his body. Guyton teaches that if a diver is brought to the surface slowly, or placed in a decompression chamber, or hyperbaric chamber where it is known to deliver oxygen or helium-oxygen gas mixtures so "the dissolved nitrogen is eliminated through his lungs rapidly enough to prevent decompression sickness. Approximately two-thirds of the total nitrogen is liberated in one hour and about 90 percent in six hours (which teaches that method is carried out to effect a 50-90% or more washout of nitrogen from the body and to carry out the method

for a minimum of 30 minutes up to 72 hours)." Therefore what is taught by Guyton is the use of a decompression chamber, or hyperbaric chamber to effect a 50-90% or more washout of nitrogen gas from the body which would inherently include, body water, ischemic tissues, and mitochondria in order to allow the reuptake of oxygen in hypoxic mitochondria and restore oxidative metabolism to affected tissues, the administration of said gas mixture being implemented for a minimum of 30 minutes up to 72 hours to assure optimum therapy and minimize cell death. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of delivering a helium:oxygen gas mixture to a patient for the treatment of a myocardial infarction as taught by Garrett by delivering it within a decompression or hyperbaric chamber because it is well known in the art that the delivery of an oxygen or helium-oxygen gas mixture within a decompression chamber for a minimum of 30 minutes up to 72 hours to assure optimum therapy and minimize cell death can effect to a 50-90% or more washout of nitrogen gas from they body, body water, ischemic tissues , and mitochondria in order to allow the reuptake of oxygen into hypoxic tissues, and mitochondria and restore oxidative metabolism to affected tissues. What is taught by Hood et al. is the use of a hyperbaric chamber (Col. 7, lines 44-46), or self contained transportable life support system (10) for the treatment of patient's following reversible vascular occlusions in a cerebrovascular accident (stroke; Col. 1, lines 22-27), the administration of said gas mixture from a suitable supply source (50; Col. 11, lines 29-37) and being implemented during patient transport or upon admission to the hospital as quickly as possible following the vascular event (Col. 1, lines 30-55).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method disclosed by Garret/Guyton by delivering a gas such as oxygen or gas mixture as taught by Garrett from a suitable supply source and being implemented during patient transport or upon admission to the hospital as quickly as possible preferably during the "golden hour" following the vascular event because as stated by Hood et al. "the need to transport medical patients and persons suffering from various medical emergency conditions such as heart attacks, strokes, etc. is well known. Medical personnel speak of a "golden hour" within which such a medical patient must be transported to a medical facility so that proper medical care can be provided therefore. The survival rate for such medical patients is greatly enhanced if they are transported to the medical facility within the golden hour."

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure. US 6983749 and US 6592848.

7. An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site http://www.uspto.gov in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amadeus S Lopez
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Art Unit 3743

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